Attachment 3
02.11.2002

K014174

510(k) SUMMARY

FEB 2 2 2002

A. Submitter's Name and Address
Barnstead/Thermolyne Corp.
P.O. Box 797
Dubuque, IA 52004

B. Contact Person
Mia M. Ware
Regulatory Affairs Specialist
563-556-2241 Ext. 485
Fax: 563-557-0612

C. Establishment Registration Number of Submitter

1950043

D. Contract Manufacturing Facility

Not Applicable

E. Device Name

Proprietary Name: Harvey® PV Dry
Common Name: Steam Sterilizer
Classification Name: Steam Sterilizer

F. Device Classification

Class II §880.6880

G. Action Taken to Comply with Section 514 of the Act

The Agency has recognized the ANSI/AAMI ST55, Tabletop Steam Sterilizers, and the FDA Guidance on Premarket Notification Submissions for Sterilizers Intended for Use in Health Care Facilities, March 1993, and its addendum, dated September, 1995. Conformance or variance with these standards is described on the following pages.

H. Reason for 510(k) Submission

- ☒ Initial Product Introduction
- ☐ New Model for Product-line Extension
- ☐ Initial Import into the USA
- ☐ Other (Include in Part IV an explanation referenced to Part I. H.)

I. Predicate Device: Harvey® MC10 Steam Sterilizer, K924955

Attachment 3
02, 11, 2002

Description of the Device: The Harvey® PV Dry is a pre/post-vacuum table top steam sterilizer. Its enclosure is made of painted metal and door cover is made of plastic. The outside dimensions are 15.5"Hx19"Wx23"D, it weighs 115lbs and the chamber is 10" in diameter. The chamber is made from stainless steel rated at 45 psig to comply with the American Society of Mechanical Engineers (ASME) Pressure Vessel Code.

Intended Use of the Device: The Harvey® PV Dry is a pre/post-vacuum table top steam sterilizer that is designed for use in medical and dental offices, hospitals, clinics, and other facilities where a variety of materials require sterilization. Intended for sterilization of wrapped or unwrapped instruments, dental handpieces, and linen packs.

Technological Characteristics: The Harvey® PV Dry has very similar technological characteristics as the predicate device, Harvey® MC10 Steam Sterilizer. The Harvey® PV Dry is a table-top autoclave steam sterilizer with pre-vacuum air removal and sterile post-vacuum drying, similar to larger hospital type units.

The Harvey® PV Dry provides superior performance for dental handpieces and difficult to penetrate fabric packs and superior and rapid drying for all loads. With sterile vacuum drying, the Harvey® PV Dry is recommended for medical and dental offices where packs, bagged instruments, and wrapped instrument sets, such as surgical kits are stored for later usage. The integral sterile drying in a 30-40 minute cycle, gives assurance of sterile conditions of the instruments at the time of delivery to the operatory. Sterile vacuum drying eliminates the need for extended drying cycles using non-sterile air.

Some features unique to the Harvey® PV Dry also demonstrate safety as well as the efficiency of the unit. The interlocking device on the door prevents manual opening until the chamber pressure decreases to near atmospheric pressure. Other technologies which help in the convenience and ease of operation of the Harvey® PV Dry include indicator lights to tell the user when the waste tank needs to be emptied, and controls preventing the running of a cycle until it is drained, indicator lights telling the user when the water supply needs to be replenished, and cycle parameter display. In the predicate device comparison matrix in Section II, there are detailed differences and similarities between the Harvey® PV Dry and its predicate device, Harvey® MC10 Steam Sterilizer.

Non-clinical Testing: Validation studies were conducted by SPS Medical Supply Corporation located at 6789 West Henrietta Road, Rush, NY 14543. Validation testing is in accordance with ANSI/AAMI ST55, ANSI/AAMI ST37. Since neither standard specifically addresses handpiece cycle validation, additional handpiece cycle validation testing was performed with the protocol being written in accordance with FDA Draft Guidance Document on Dental Handpieces, 1995, and the Guidance on Premarket Notification Submissions for Sterilizers Intended for Use in Health Care Facilities, 1993. Successful sterilization was achieved in all three validations and the declarations of conformity to the consensus standards are located in Section III. Testing results and raw data are contained in the product's device master record.

Conclusion: It is Barnstead/Thermolyne's conclusion that the Harvey® PV Dry is substantially equivalent to its predicate device, the Harvey® MC10 Steam Sterilizer. Based on the validation results and information submitted, the Harvey® PV Dry provides effective sterilization of the indicated medical and dental materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2002

Barnstead/Thermolyne Corporation
C/O Mr. Reiner Krumme
Responsible Third Party
TUV Rheinland of North America, Inc
12 Commerce Road
Newton, Connecticut 06470

Re: K014174
Trade/Device Name: Harvey PV Dry Sterilizer, Model # ST127325; ST127320
Regulation Number: 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: February 12, 2002
Received: February 13, 2002

Dear Ms. Krumme:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 4
02.11.2002

INDICATIONS FOR USE STATEMENT

510(k) Number : 014174

Device Name: Harvey® PV Dry

Indications for Use:

The Harvey® PV Dry is a prevacuum and post vacuum drying sterilizer intended to provide sterilization of medical and dental instruments. It is intended to provide sterilization of wrapped or unwrapped metal instruments, surgical devices and other heat stable devices in pouches, surgical packs, dental handpieces, and linen packs. Deionized or distilled water is required for operation of the Harvey® PV Dry.

The sterilizer has four standard cycles: Unwrapped Instruments (135C for 3 minutes); Wrapped Instruments (135C for five minutes); Packs (121C for 30 minute); Special, for dental handpieces (5 minutes at 134C). There is also an accessible Bowie-Dick test cycle for routine testing of the steam penetration capability into packs. The parameters are fixed for each cycle.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optonal Format 3-10-98)

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
510(k) Number K014174